THIS OPINION IS NOT FOR PUBLICATION
WITHOUT APPROVAL OF THE COMMITTEE ON OPINIONS

IN RE: DIET DRUG LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION: BERGEN COUNTY Master Docket No.: BER-L-13379-04MT Civil Action **OPINION**
FRANKIE A. BRIGMAN, Plaintiff, v. WYETH, Defendant.	Docket No. BER-L-2547-04MT
SARAH ANN GIBSON, Plaintiff, v. WYETH, Defendant.	Docket No. BER-L-2561-04MT

PAMELA L. GRABER-KEITH, Plaintiff, v. WYETH, Defendant.	:	Docket No. BER-L-2562-04MT
LEA M. MORRISON, Plaintiff, v. WYETH, Defendant.	:	Docket No. BER-L-2565-04MT
ELIZABETH WARD, Plaintiff, v. WYETH, Defendant.	:	Docket No. BER-L-2571-04MT

Decided: April 7, 2005

Esther E. Berezofsky, Esq., Williams, Cuker & Berezofsky and Avram J. Blair, Esq., Williams Bailey Law Firm, LLP, appearing on behalf of plaintiffs.

Anita Hotchkiss, Esq. and Charles E. Erway, III, Esq., Porzio, Bromberg & Newman, P.C., and Anand Agneshwar, Esq., Arnold & Porter, LLP, appearing on behalf of defendant Wyeth Corporation.

Walsh, J.S.C.

The Court has scheduled thirteen (13) cases for trial on May 31, 2005.[1] These cases involve two (2) prescription diet drugs approved by the United States Food & Drug Administration ("FDA") for the treatment of obesity. The drugs, Pondimin® and Redux™, were marketed by Wyeth, which was formerly known as American Home Products Corporation ("AHP"). In 1973, the FDA approved the New Drug Application ("NDA") for Pondimin®, finding it to be safe and effective for the obesity indication.[2] In April 1996, the FDA approved Redux™, the other drug in question, which was thereafter marketed by AHP and another company. Plaintiffs claim that Pondimin® and Redux™ ("phen-fen")[3] cause valvular heart

[1] Following the procedure discussed in its Opinion, *In re Diet Drug Litigation*, BER-L-7718-03 (August 4, 2004), the Court has consolidated five (5) cases for trial: *Frankie A. Brigman v. Wyeth,* BER-L-2547-04, *Sarah Ann Gibson v. Wyeth,* BER-L-2561-04, *Pamela L. Graber-Keith v. Wyeth*, BER-L-2562-04, *Lea M. Morrison v. Wyeth*, BER-L-2565-04, and *Elizabeth Ward v. Wyeth*, BER-L-2571-04, with the remaining cases serving as backups (*Inez E. Bryant v. Wyeth*, BER-L-2549-04, *Sheila M. Allen v. Wyeth*, BER-L-5599-03, *Marolyn J. Efird v. Wyeth*, BER-L-2554-04, *Naida Caterina v. Wyeth*, BER-L-2551-04, *Patricia Gauthier v. Wyeth*, BER-L-2559-04, *Linda Segal v. Wyeth*, BER-L-2567-04, *Marion "Frances" Sholar v. Wyeth*, BER-L-2568-04, and *Shirley A. White v. Wyeth*, BER-L-2572-04).

[2] Both Pondimin® and Redux™ are anoretics. They operate as obesity drugs by causing a decrease in appetite. *Stedman's Medical Dictionary* 90 (25th ed. 1990). Both drugs appear to limit caloric intake by increasing serotonin levels in brain synopses. Redux™ Package Insert, April 29, 1996.

[3] The term phen-fen, which is often written fen-phen, refers to the use of fenfluramine or dexfenfluramine in combination with phentermine. For purposes of this Opinion, phen-fen will refer to fenfluramine or dexfenfluramine, whether used in combination with phentermine or not.

disease and that Wyeth should have warned the plaintiffs' health care providers of that risk.[4]

On July 8, 1997, physicians at the Mayo Clinic publicly reported findings of unusual heart valve lesions and/or valvular regurgitation in twenty-four (24) patients being treated for obesity with phen-fen.[5] Simultaneously, the FDA issued a Public Health Advisory to health care professionals notifying them of the twenty-four (24) Mayo Clinic cases and nine (9) additional cases of "unusual valvular morphology and regurgitation" in women who had received phen-fen therapy for an average of ten (10) months. From that time forward, and until Pondimin® and Redux™ were withdrawn from the market some nine (9) weeks later, these findings and subsequent developments related to them were widely reported in the media.[6]

On July 24, 1997, Wyeth issued a "Dear Doctor Letter" to health care providers nationwide notifying them that the labeling for Pondimin® and Redux™ would be revised to include a black box warning concerning a "potentially serious

---

[4] Wyeth and related entities agreed to settle personal injury claims of U.S. Pondimin® and Redux™ users in a 1999 Nationwide Class Action Settlement Agreement ("CAS"). *See In re Diet Drugs (Phentermine, Fenfluramine, Dexfenfluramine) Prod. Liab. Litig.*, 2000 WL 1222042 (E.D. Pa. Aug. 28, 2000) (certifying class and approving settlement), *aff'd*, 275 F.3d 34 (3d Cir. 2001). The plaintiffs here claim the right to sue Wyeth pursuant to certain limited "downstream opt out" rights available under the CAS. *See* CAS, § IV.D.3. & 4.

The plaintiffs have not claimed that Wyeth had a duty to warn them directly of the potential risks of valvular disease. *See Perez v. Wyeth Labs., Inc.*, 161 N.J. 1 (1999). *See generally* Timothy S. Hall, *Reimagining The Learned Intermediary Rule For The New Pharmaceutical Marketplace*, 35 Seton Hall L. Rev. 193, 213-216 (2004).

[5] July 8, 1997, Mayo Clinic press release. Dr. Heidi M. Connolly subsequently published a case series about these twenty-four (24) patients. Heidi M. Connolly, et al., *Valvular Heart Disease Associated with Fenfluramine-Phentermine*, N.Engl.J.Med. 337:581 (Aug. 28, 1997).

[6] The FDA republished its Health Advisory in the *Journal of the American Medical Association*. *Health Advisory on Concomitant Fenfluramine and Phentermine Use*, JAMA, 278:5:379 (Aug. 6, 1997).

and unusual form of valvular heart disease … reported in patients taking fenfluramine and phentermine." The letter also advised that concomitant use of Pondimin® with other weight-loss agents was neither recommended nor FDA approved.

On August 29, 1997, the FDA approved revised labeling for Pondimin® that included a black box warning for valvular heart disease. The updated warning included the following:

> Fenfluramine has been reported to be associated with the occurrence of serious regurgitant cardiac valvular disease, including disease of the mitral, aortic and/or tricuspid valves. In one literature report, 24 patients, who received combination therapy with fenfluramine and phentermine for treatment of obesity, were found to have regurgitant cardiac valvular disease; five of these patients required valvular surgery…. In these reports and other reported cases, fenfluramine was generally taken in combination with phentermine. However, there are some reports in which the valvular disease was seen in patients taking fenfluramine alone.

The FDA approved similar revised Redux™ labeling on September 3, 1997. Shortly thereafter, however, additional adverse information became available, and Wyeth withdrew Pondimin® and Redux™ from the market on September 15, 1997. Plaintiffs argue that the Pondimin® and Redux™ labeling should have included information on the risk of valvular heart disease.

In its August 4, 2004 Opinion dealing with the question of consolidation, this Court indicated that the "heeding presumption" as articulated in *Coffman v.*

Keene Corp., 133 N.J. 581 (1993), would likely be applicable in these prescription drug product liability cases. Wyeth now seeks a ruling that the heeding presumption is inapplicable in cases where the drug product can only be obtained by prescription. In Wyeth's view, the heeding presumption should not be available where a learned intermediary -- the physician -- ultimately makes the prescribing decision. *See* Section 4 of the Product Liability Act ("PLA"), **N.J.S.A.** 2A:58C-4; *Niemiera v. Schneider*, 114 N.J. 550, 559 (1989) (noting no duty to warn patient directly about the risks of DPT vaccine).

The Court finds that application of the heeding presumption is appropriate in pharmaceutical product liability cases such as these. A heeding presumption will serve to shift to Wyeth the burden of going forward with evidence on the issue of whether a physician armed with appropriate risk information concerning the possibility of associated valvular disease nevertheless would have prescribed Pondimin® and/or Redux™. But the presumption, if rebutted, will vanish in accordance with **N.J.R.Evid.** 301 and *Sharpe v. Bestop, Inc.*, 314 N.J. Super. 54, 68-69 (App. Div. 1998), *aff'd o.b.*, 158 N.J. 329 (1999), and the plaintiffs ultimately will bear the burden of proof on this proximate cause issue. The reasons for this ruling follow.

I

A.

The New Jersey Supreme Court adopted the "heeding presumption" for use in product liability cases in *Coffman*, 133 N.J. at 595-603. There, the plaintiff, a former naval electrician, was exposed to asbestos while working over an extended period in close quarters on naval vessels. The plaintiff ultimately retired from his work at the Philadelphia naval shipyard after eighteen (18) years. Some sixteen (16) years later, the plaintiff learned he suffered from asbestos-related injuries. A product liability action followed.

During the trial, the defendant argued that the plaintiff must establish that its failure to warn with respect to the asbestos products in question was a proximate cause of his injuries. The trial court disagreed and instructed the jury "that it should presume that if defendant had provided an adequate warning, it would have been followed." *Coffman*, 133 N.J. at 593. The question of whether such a heeding presumption should have been given ultimately reached the New Jersey Supreme Court.

In endorsing the heeding presumption, the *Coffman* Court conceded that such a rule is not a "natural" or "logical" presumption. *Id.* at 597.[7] Rather, the

[7] In so finding, the Supreme Court did not rest its conclusion on the RESTATEMENT (SECOND) OF TORTS § 402A cmt. j, as have many courts. *Compare Coffman*, 133 N.J. at 596 with *Technical Chem. Co. v. Jacobs*, 480 S.W.2d 602, 606 (Tex. 1972); *Precise Eng'g v. LaCombe*, 624 So.2d 1339, 1341 (Ala. 1993); *Dias v. Daisy-Heddon*, 390 N.E.2d

heeding presumption was to be grounded in public policy:

> We can agree with defendant that the heeding presumption is not firmly based on empirical evidence. It is not therefore a "natural" or "logical" presumption….
>
> Nevertheless, the creation of a presumption can be grounded in public policy…. Although empirical evidence may not demonstrate the soundness of a heeding presumption, an examination of the strong and consistent public policies that have shaped our laws governing strict products liability demonstrates the justification for such a presumption.
>
> The use of presumptions grounded in public policy is not novel. We have often adopted or used presumptions in that context in order to advance our goals of fostering greater product safety and enabling victims of unsafe commercial products to obtain fair redress. The concept of strict products liability itself "arose in part because of a basic presumption that persons not abusing products are not usually injured unless a manufacturer failed in some respect in designing, manufacturing or marketing the product."

See Coffman, 133 N.J. at 597-598 (citations omitted). The public policy goals articulated included: focusing on the underlying purpose of product liability law which concentrates on a product rather than a defendant's negligence; encouraging "manufacturers to produce safer products, and to alert users of the hazards arising from the use of those products through effective warnings"; simplifying the trial

---

222, 225 (Ind. App. 1979); *Wooderson v. Ortho Pharm. Corp.*, 681 P.2d 1038, 1057 (Kansas), *cert. denied,* 469 U.S. 965 (1984); *Seley v. G.D. Searle & Co.*, 423 N.E.2d 831, 838 (Ohio 1981). Professors James A. Henderson and Aaron D. Twerski, the co-reporters of the RESTATEMENT (THIRD) OF TORTS (PRODUCT LIABILITY*)* (1997), have argued that the heeding presumption is based on a misinterpretation of comment j to RESTATEMENT (SECOND) OF TORTS § 402A (1965). *See* James A. Henderson, Jr. & Aaron D. Twerski, *Doctrinal Collapse in Products Liability: The Empty Shell of Failure to Warn*, 65 N.Y.U. L. Rev. 265, 278-279, 325-326 (1990).

process and plaintiff's burden of proof; and, minimizing the likelihood that causation decisions will be based on unreliable evidence. *Coffman*, 133 N.J. at 599.

The same day the Supreme Court endorsed the heeding presumption it also extended it to encompass warnings given to a plaintiff's employer. In *Theer v. Philip Casey Co.*, 133 N.J. 610 (1993), the Court recognized that when equipment is used in the workplace, the employer ordinarily is the entity receiving risk information from the manufacturer. *Id.* at 621. Consequently, to establish a proximate cause defense "the manufacturer must show that had an adequate warning been provided, the employer itself would not have heeded the warning by taking reasonable precautions for the safety of its employees and would not have allowed its employees to take measures to avoid or minimize the harm." *Theer*, 133 N.J. at 621 (citing *Coffman*, 133 N.J. at 609).

B.

Wyeth claims that despite the holdings in *Coffman* and *Theer* this Court should not apply the heeding presumption in a pharmaceutical product liability lawsuit. This is so, according to Wyeth, because shortly before it decided *Coffman*, the Supreme Court reversed the Appellate Division in a pharmaceutical product liability failure to warn case implicating the proximate cause issue. *Strumph v. Schering Corp.*, 133 N.J. 33 (1993).

In *Strumph*, there was unrebutted testimony from the plaintiff's treating physicians that they would have prescribed a particular neuroleptic medication, Trilafon, even had a more detailed and specific warning about a serious side effect been given.[8] *Strumph v. Schering Corp.*, 256 N.J. Super. 309 (App. Div. 1992), *rev'd on dissent*, 133 N.J. 33 (1993). The Appellate Division found that testimony insufficient to support the trial court's grant of summary judgment. *Id.* Essentially, the Appellate Division majority found that the treating physicians' testimony on the proximate cause issue itself presented a triable issue of fact -- the jury could reject the doctors' assertion that in the face of a more detailed and specific warning from the pharmaceutical company, they nevertheless would have prescribed the drug. *Id.* at 320-321.

Judge Skillman dissented and opted for the traditional proximate cause formulation as it then stood in pharmaceutical product liability cases. According to him, the plaintiff in such a case "must show that adequate warnings would have altered her doctors' decision to prescribe Trilafon." *Strumph*, 256 N.J. Super. at 323 (Skillman, J.A.D., dissenting). As noted, the Supreme Court supported that view and reinstated the original grant of summary judgment "substantially for the

[8] The side effect reported was neuroleptic malignant syndrome ("NMS"). The plaintiff here was diagnosed as a paranoid schizophrenic. At the time plaintiff received Trilafon, Schering Corporation had provided warning information that NMS was "a relatively uncommon, potentially lethal syndrome, characterized by severe extrapyramidal dysfunction, with rigidity and eventual stupor or coma; hyperthermia and autonomic disturbances, including cardiovascular effects. There is no specific treatment, the neuroleptic drug should be discontinued." In 1990, the company moved the information to the "warnings" section of the labeling and gave the information significantly greater prominence.

reasons expressed in Judge Skillman's dissenting opinion." *Strumph*, 133 N.J. at 34.

Wyeth claims that *Strumph* controls the disposition in this case because the Supreme Court heard oral argument in *Strumph* one (1) day after oral argument in *Coffman*. Moreover, the Supreme Court's decisions in *Strumph* and *Coffman* were published within two (2) weeks of each other though *Strumph* preceded *Coffman*. According to Wyeth, the Supreme Court's contemporaneous consideration of *Strumph* and *Coffman* strongly suggests that it did not intend to extend the heeding presumption to prescription drugs. This Court rejects Wyeth's argument as unsupported speculation. In short, *Strumph* is not controlling precedent concerning the proper allocation of the burdens of proof respecting proximate cause in pharmaceutical product liability cases where the underlying claim is based on an alleged failure to warn.

II

A.

It is an accepted tenet of product liability law that even where a product is properly designed and manufactured, it may be unsafe for its intended or foreseeable uses if it is not accompanied by adequate directions for its use. **N.J.S.A.** 2A:58C-4. This principle comes from the common law rule that "the supplier of a product not intrinsically defective either in its manufacture or design

is nevertheless obliged to warn the consumer of dangers inherent in its use which are known to the manufacturer but of which the consumer is unlikely to be aware." *Torsiello v. Whitehall Lab.*, 165 N.J. Super. 311, 320 (App. Div.), *certif. denied,* 81 N.J. 50 (1979). Accordingly, manufacturers must provide consumers with warnings or instructions about "dangers of which they know or should have known on the basis of reasonably obtainable or available knowledge." *Feldman v. Lederle Lab.*, 97 N.J. 429, 434 (1984).

Normally, this duty is discharged by warnings or instructions being provided directly to the consumer. *Torsiello*, 165 N.J. Super. at 323. However, shortly after passage of the Federal Food Drug and Cosmetic Act ("FDCA") in 1938, the FDA launched a series of regulatory initiatives which created the prescription drug category. Prior to these regulatory initiatives, all non-narcotic drugs could be purchased by the public without the intervention of a health care professional. "The FDA's actions were motivated by a recognition that patients could not use some drug products safely without the aid of a physician. The FDA regulatory policy of directing information about the risks and benefits of this class of drugs to physicians was statutorily confirmed by amendments to the FDCA in 1951." Charles J. Walsh, et al., *The Learned Intermediary Doctrine: The Correct Prescription for Drug Labeling*, 48 Rutgers L. Rev. 821, 822 (1996) (footnotes omitted).

By the same token, the provision of warning information and instructions for use of prescription drugs to health care providers is critically important. As commentators have noted:

> Prescription drugs are classic examples of "credence goods" -- products whose qualities cannot be assessed by the consumer through normal use. Hence, information about the proper use of such products is often as valuable to health care professionals as the actual product itself. Even sophisticated health care professionals depend on pharmaceutical manufacturers to provide accurate and reliable information about when and how to use their products.

Charles J. Walsh and Alissa Pyrich, *FDA Efforts to Control the Flow of Information at Pharmaceutical Industry-Sponsored Medical Education Programs: A Regulatory Overdose*, 24 Seton Hall L. Rev. 1325, 1330-1331 (1994) (footnotes omitted).

The significant differences in the dispensing of prescription drugs and the provision of warnings and other prescribing information with respect to them led courts to develop the learned intermediary doctrine in the mid-1960s. *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966).[9] As the Appellate Division explained:

---

[9] The United States Court of Appeals for the Eighth Circuit created the phrase "learned intermediary" in this now famous quotation:

> [I]n this case we are dealing with a prescription drug rather than a normal consumer item. In such a case *the purchaser's doctor is a learned intermediary between the purchaser and the manufacturer*. If the doctor is properly warned of the possibility of a side effect in some patients, and is advised of the

> Ordinarily in the case of prescription drugs warning to the prescribing physician is sufficient. In such cases the choice involved is essentially a medical one involving an assessment of medical risks in the light of the physician's knowledge of this patient's needs and susceptibilities. Further it is difficult under such circumstances for the manufacturer, by label or direct communication, to reach the consumer with a warning. A warning to the medical profession is in such cases the only effective means by which a warning could help the patient.

Bacardi v. Holzman, 182 N.J. Super. 422, 425 (App. Div. 1981) (citation omitted).

The New Jersey Supreme Court formally adopted the learned intermediary doctrine in *Niemiera v. Schnieder*, 114 N.J. 550, 559 (1989). In doing so, the Court recognized that the PLA, passed by the Legislature in 1987, had codified the doctrine through its definition of an "adequate warning or instruction" for a prescription drug. **N.J.S.A.** 2A:58C-4; *Niemiera*, 114 N.J. at 561. Under the PLA, adequate directions for a prescription drug "tak[e] into account the characteristics

---

> symptoms normally accompanying the side effect, there is an excellent chance that injury to the patient can be avoided. This is particularly true if the injury takes place slowly, as is the case with the injury in question.

Sterling Drug, 370 F.2d at 85 (emphasis added).

In *Gravis v. Parke-Davis & Co.*, 502 S.W.2d 863 (Tex. Civ. App. 1973), the plaintiff sought damages from the drug's manufacturer under a failure-to-warn theory. The manufacturer had provided a warning to the physician but not to the patient. The Court there dismissed the action with the most limited view of the learned intermediary doctrine, stating: "We believe that it was unreasonable to suppose that a drug manufacturer must go beyond the physician and give actual warnings to the patient. Once the physician has been warned, the choice of which drugs to use, and the duty to explain the risks involved, is his." *Id.* at 870. Three reasons for not requiring a drug manufacturer to warn the patient directly were given by that Court: (1) "The entire system of drug distribution in America is set up so as to place the responsibility of distribution and use upon professional people"; (2) "professionals are in the best position to evaluate the warnings put out by the drug industry"; and (3) "[g]enerally speaking, only a physician would understand the propensities and dangers involved." *Id.* New Jersey has never accepted such a rigid interpretation of this doctrine.

of, and the ordinary knowledge common to, the prescribing physician." **N.J.S.A.** 2A:58C-4. [10]

B.

As New Jersey's courts refined their treatment of the learned intermediary doctrine, they revisited the question of what standard should be used to assess whether a health care provider had obtained a patient's informed consent for a medical procedure. Prior to *Largey v. Rothman*, 110 N.J. 204 (1988), New Jersey applied the so-called "professional" standard in determining whether a physician had obtained informed consent from his or her patient in advance of performing a medical procedure or prescribing a medication. *Kaplan v. Haines*, 96 N.J. Super. 242, 257 (App. Div. 1967), *aff'd o.b.*, 51 N.J. 404 (1968). As explained by the *Kaplan* court:

> The authorities ... are in general agreement that the nature and extent of the disclosure, essential to an informed consent, depends upon the medical problem as well as the patient. Plaintiff has the burden to prove what a reasonable medical practitioner of the same school and

[10] The legislative statement that accompanied the bill states:

> Section 4 provides that a manufacturer or seller is not liable in a warning-defect case if an adequate warning is given when the product has left the control of the manufacturer or seller or, in the case of dangers discovered after the product has left control, if an adequate warning is then given by the manufacturer or seller. *The subsection contains a general definition of an adequate warning and a special definition for warnings that accompany prescription drugs, since, in the case of prescription drugs, the warning is owed to the physician.* The subsection establishes a presumption that a warning or instruction is adequate on drug or food products if the warning has been approved or prescribed by the Food and Drug Administration.

S. Judiciary Comm. Statement No. S. 2805, L. 1987, c. 197 (emphasis added).

> same or similar community, under the same or similar circumstances, would have disclosed to his patient….

Id. at 257. The professional standard was founded on the view that "a physician and *only* a physician, can effectively estimate both the psychological and physical consequences that a risk inherent in a medial [sic] procedure might produce in a patient." *Largey*, 110 N.J. at 210.

The professional standard used to assess whether informed consent had been obtained was abandoned in *Largey*. There, the New Jersey Supreme Court shifted the focus from the physician to the patient when it adopted the informed consent calculus first proposed by the United States Court of Appeals for the District of Columbia Circuit in *Canterbury v. Spense*, 464 F.2d 772 (D.C. Cir.), *cert. denied,* 409 U.S. 1064 (1972). After *Largey*, the proper focus would not be on the conduct of the doctor but rather on what a "physician should disclose to a reasonable patient in order that the patient might make an informed decision…." *Largey*, 110 N.J. at 206. The Supreme Court, while citing several reasons for this policy shift including the strong subjective component implicit in the professional standard, found that:

> [T]he strongest consideration that influences our decision in favor of the "prudent patient" standard lies in the notion that the physician's duty of disclosure "arises from phenomena apart from medical custom and practice": the patient's right of self-determination…. The foundation for the physician's duty to disclose in the first place is found in the idea that "it is the prerogative

> of the patient, not the physician, to determine for himself the direction in which his interests seem to lie." …. In contrast the arguments for the "professional" standard smack of an anachronistic paternalism that is at odds with any strong conception of a patient's right of self-determination….

Largey, 110 N.J. at 214 (citations omitted).

III

When the Supreme Court embraced the learned intermediary doctrine in *Niemiera*, it was clear that the Court expected the risk information concerning a drug product provided to the physician be passed from him or her to the patient. In that vein, the Court wryly observed:

> Because "it is only the unavoidably unsafe [drug] product 'accompanied by proper … warning' that is not defective," … it would be the bitterest irony if the learned intermediary were to be excused from performing the very act that makes the product safe, that is, giving proper warning of the danger or side effects of the product. The concept of proper warning by the learned intermediary will blend in this context with the concept of informed consent. Both are aspects of the patient autonomy that underlies our law of medical care…. We recently had occasion to refine our understanding of the informed consent doctrine in *Largey v. Rothman*, 110 N.J. 204 … (1988). We there clarified that under appropriate principles of New Jersey tort law, a physician must disclose to a patient all material information that a "prudent patient" might find significant for a determination whether to undergo the proposed therapy…. Such a standard is appropriately relevant in the case of failure to warn with respect to the adverse consequences of pharmaceutical products. As counsel for Wyeth put it, "[t]he duty of the manufacturer of the

> vaccine is to warn the learned intermediary who passes it on to the patient through informed consent." We have emphasized that "[w]hen the strict liability defect consists of an improper … warning, reasonableness of the defendant's conduct is a factor in determining liability."

Niemiera, 114 N.J. at 562-563 (citations omitted).

This Court finds that *Niemiera*, *Largey* and their progeny articulate the strong public policy that material information about risks and benefits of a drug product be received by the patient. *See Matthies v. Mastromonaco*, 310 N.J. Super. 572, 593 (App. Div. 1998), *aff'd*, 160 N.J. 26 (1999) (noting that the test for determining whether a particular peril must be divulged is its materiality to patient's decision; all risks potentially affecting the decision must be unmasked). That policy objective is furthered by the heeding presumption. In modern medicine, the decision-making process as to whether or not to employ a particular recommended treatment, including the use of prescription drugs, is collaborative. The physician should explain to the patient the risks and benefits of the medical procedure, as well as any reasonable alternatives. Ultimately, the patient, armed with this information, makes the decision whether to proceed. In cases where the warning or instruction is given to the consumer, New Jersey law has embraced the heeding presumption. Because the heeding presumption in the pharmaceutical product liability context assumes the communication of risk information from the physician to the patient, the presumption furthers New Jersey's public policy of

communicating risk information. Moreover, the other policy considerations articulated in *Coffman* -- product focus, effective warnings, simplification and reliability -- apply with equal force as well.

Wyeth disagrees. As Wyeth sees it, the heeding presumption only has limited utility in the product liability field.[11] It certainly should not be applied in the pharmaceutical product liability context. Wyeth, in this regard, writes:

> Because all prescription pharmaceuticals pose unavoidable risks, risk information is included in pharmaceutical labeling so that the learned intermediary, in his or her professional judgment, can take such information or "warnings" into consideration when balancing the risks of the drug with the potential benefits for a particular patient. This information is not "heeded" in the sense that a product end-user can follow or obey a safe use instruction and thereby *avoid* a risk. Rather, risk information merely becomes an additional element in a prescribing physician's risk-benefit calculus.
>
> Consequently, it cannot reasonably be suggested or assumed that "heeding" risk information in prescription drug labeling would lead a physician *not* to prescribe the drug. Indeed, most prescription drugs have been reported to be associated with significant risks in at least some patients. Nonetheless, all FDA-approved drugs, by definition, have been found to be "safe and effective" and are prescribed by doctors despite such risks.

[11] There is a difference in the use of the heeding presumption in no warning cases such as *Coffman,* 133 N.J. 581, and these phen-fen cases as opposed to inadequate warning cases where the manufacturer made some attempt to provide this information but it is claimed that the information could have been more clearly stated or more prominently displayed. In the latter case, commentators have argued against the use of the heeding presumption. Karin L. Bohmholdt, *The Heeding Presumption and Its Application: Distinguishing No Warning From Inadequate Warning*, 37 Loy. L.A. L. Rev. 461 (2003). Despite this apparent difference, New Jersey courts have been disinclined to apply the heeding presumption differentially. *Sharpe v. Bestop, Inc.*, 314 N.J. Super. 54 (App. Div. 1998).

Brief in Support of Heeding Presumption Motion ("Wyeth brief") (footnotes omitted) (alternations in original).

The Court rejects this argument out of hand. First, the New Jersey Supreme Court has found that the heeding presumption has utility. Second, it is apparent to the Court that the Supreme Court sees the learned intermediary doctrine and the post *Largey* informed consent regime as operating hand in hand. Because the physician is in the best position to receive and assess risk information, it is appropriate that warnings or other risk information be provided to him or her. But that is but the start of information exchange. Here, there is little doubt under *Largey* that the health care professional must convey to the patient the information on the potential risk of phen-fen causing valvular disease. While the law leaves the health care provider free to decline to prescribe the pharmaceutical product, the doctrine of informed consent requires the patient to determine whether he or she wishes to take the drug product in the first place. Wyeth's desire to leave the prescribing decision solely in the hands of the learned intermediary runs afoul of New Jersey's public policy.

Next, Wyeth seeks to change the debate from whether risk information should be provided to how prescribing decisions are made in the face of so-called unavoidable risks. In this regard, Wyeth writes that "whether a physician would have prescribed a drug if additional risk information had been provided is a far

different question from whether a consumer would have heeded, *i.e.*, followed or obeyed, safe use warning instructions such as those regarding proper use of a chemical or mechanical product."[12] Wyeth brief.

While the Court agrees that instructional information and risk information may lead to a different decision-making process, that is beside the point.[13] There may be circumstances where the need for the medication is so dire and the risk so small that one might question how a reasonable patient could refuse the treatment. Perhaps the risk may be so remote and the benefit so apparent that the physician

---

[12] In *Thomas v. Hoffman-LaRoche, Inc.*, the Fifth Circuit noted:

> Because the precautions are typically minimal (*i.e.*, store the pressurized can away from the water heater), we have little trouble with a rebuttable presumption that a reasonable product user will choose to use the product safely. The choice, however, presented by the unavoidable risk warning is not between the safe use and the unsafe use of a product, but between using and not using the product. The consumer can choose to use the product and face its risks, or choose not to use the product and lose its potential benefits. Generally, using the product will present the less risky of these two alternatives. Consider the polio vaccine in *Reyes* [*v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir.), *cert. denied,* 419 U.S. 1096 (1974)]. There is a risk of contracting polio if a person uses the vaccine, and there is a risk if the person decides not to use the vaccine. Presumably, the risk of contracting polio is less with the vaccine than without it. If we assume that the average user will take the less risky alternative, the average user will choose to take the vaccine, and a warning detailing the unavoidable risks of the polio vaccine, whether given or not, would not change that decision. Unless the plaintiff can establish that using the product is, for the average consumer, the more risky alternative, the *Reyes* rule that the consumer will act to minimize his level of risk, if applied in the context of an unavoidable risk, would seem to establish a rebuttable presumption that the consumer would not have changed his decision to use the product if warned of the unavoidable risk. 949 F.2d 806, 813-814 (5th Cir.), *cert. denied*, 504 U.S. 956 (1992) (footnote omitted).

[13] In addition to the *Thomas* case, Wyeth points to other courts which have declined to apply the heeding presumption in pharmaceutical product liability cases. *See Odom v. G.D. Searle & Co.*, 979 F.2d 1001 (4th Cir. 1992) (applying South Carolina law); *Motus v. Pfizer, Inc.*, 196 F. Supp. 2d 984 (C.D. Cal. 2001) (applying California law), *aff'd* 358 F.3d 659 (9th Cir. 2004); *In re: Rezulin Prod. Liab. Litig.*, 331 F. Supp. 2d 196 (S.D.N.Y. 2004) (applying Texas law).

The Court believes these cases have little persuasive value because New Jersey has already adopted the heeding presumption in *Coffman*. The federal cases reported by Wyeth do nothing more than apply state law in these diversity cases.

would be privileged to make the prescribing decision without informing his or her patient. *Blazoski v. Cook*, 346 N.J. Super. 256, *certif. denied,* 172 N.J. 181 (2002). But that does not appear to be the case here. While obesity is a serious condition, phen-fen is hardly its only cure. While phen-fen may have provided real benefits for those who took it, these patients were entitled to know of its risks. And it is certainly foreseeable that, if advised of the risks, they might well have chosen alternatives.

Of course, such issues, key to the resolution of proximate cause, in the absence of the heeding presumption, must be resolved on the basis of highly speculative testimony where no warning information was conveyed by the drug product's manufacturer. *Coffman* addressed the problem of eliciting speculative evidence where the warning would have been directly conveyed. It seems that the heeding presumption addresses this important consideration equally where a learned intermediary is involved. Using the heeding presumption in both instances results in a better trial process; minimizing the jury's required use of highly speculative evidence as to what the plaintiff might have done had risk information been disclosed.

IV

Despite the heeding presumption, Wyeth can still prevail on this proximate issue. As noted in **N.J.R.Evid.** 301, once the party against which the presumption

has been applied produces sufficient evidence to rebut it[14] the presumption disappears:

> [A] presumption discharges the burden of producing evidence as to a fact (the presumed fact) when another fact (the basic fact) has been established.
>
> If evidence is introduced tending to disprove the presumed fact, the issue shall be submitted to the trier of fact for determination unless the evidence is such that reasonable persons would not differ as to the existence or nonexistence of the presumed fact. If no evidence tending to disprove the presumed fact is presented, the presumed fact shall be deemed established if the basis fact is found or otherwise established. *The burden of persuasion as to the proof or disproof of the presumed fact does not shift to the party against whom the presumption is directed unless otherwise required by law*.

N.J.R.Evid. 301 (emphasis added).

In *Sharpe v. Bestop, Inc.*, 314 N.J. Super. 54 (App. Div. 1998), *aff'd o.b.*, 158 N.J. 329 (1999), the Appellate Division examined the use of the heeding presumption in a "second collision" product liability case. There, the plaintiff was driving a customized Jeep CJ7 when he apparently fell asleep and the vehicle struck a guardrail. The plaintiff, who was not wearing his seat belt, was ejected from the vehicle, suffering serious injuries. *Id.* at 61. In the product liability

[14] The question of how much evidence is necessary to rebut or overcome a presumption is an interesting question. Given the language of **N.J.R.Evid.** 301 and the policies expressed, it would seem that the opponent of the presumption "must produce the same amount of evidence necessary to avoid a directed verdict ... in the usual context of a civil case." Stephen A. Saltburg, et al., *Federal Rules of Evidence Manual* § 301.02 [4] (8th Ed. 2002). *See Sinatra v. Heckler*, 566 F. Supp. 1354, 1359-1360 (E.D.N.Y. 1983) ("In order to rebut the presumption that a notice of reconsideration is received five days after it is dated, the claimant must adduce evidence that would be sufficient to overcome the directed verdict....").

action that followed, plaintiff claimed he received inadequate warnings that he should use his seat belt at all times because of the customized soft top and sides which had been installed on this particular vehicle. The plaintiff lost his case even though the jury found the warning to be inadequate. The jury found that the failure to provide additional warning information was not a proximate cause of his injuries because he probably would not have followed a stronger warning to wear his seat belt. *Id.* at 61, 62.

The question before the Appellate Division was the status of the heeding presumption in the face of evidence that the warning would not have been followed. The court found that in the face of evidence sufficient to rebut the heeding presumption, the presumption vanishes and the plaintiff must establish that the failure to warn was a proximate cause of the accident. *Sharpe*, 314 N.J. Super. at 67. In so finding, the court summarized the respective burdens of the parties in a case where the heeding presumption is applicable.

> Thus, ... the heeding presumption applies to all failure to warn and inadequate warning cases and provides the plaintiff with a rebuttable presumption on the issue of proximate cause, *i.e.*, if a warning or instruction had been given, such warning or instruction would have been heeded by the plaintiff. In such cases, the burden of production on the issue of proximate cause shifts to the defendant to come forward with rebuttal evidence. In essence, the defendant's burden of production requires "evidence sufficient to demonstrate ... that a warning would have made known to the plaintiff the danger of the product and, notwithstanding the knowledge imparted by

> the warning, the plaintiff would have proceeded voluntarily and unreasonably to subject him or herself to the dangerous product." .... If the defendant fails to meet its burden of production to the trial court's satisfaction, the trial judge is required to direct a verdict in favor of the plaintiff on the issue of proximate causation. If, however, the defendant presents rebuttal evidence such that reasonable minds could differ as to whether the warning, if given, would have been heeded by the plaintiff, the defendant has satisfied its burden of production and the plaintiff loses the benefit of the presumption. The plaintiff must then carry the burden of persuasion as to proximate cause.

Sharpe, 314 N.J. Super. at 68-69 (citation omitted).

In the present case, Wyeth could rebut the heeding presumption if it produces evidence that one or more of the plaintiffs' health care professionals, if provided with the warning information, would have prescribed phen-fen anyway and would not have communicated the risk information on the increased potential for valvular disease to the plaintiffs. *See Strumph v. Schering Corp.*, 256 N.J. Super. 309 (App. Div. 1992), *rev'd on dissent*, 133 N.J. 33 (1993). In the absence of any evidence to the contrary, summary judgment for Wyeth may be appropriate. **N.J.R.Evid.** 301.

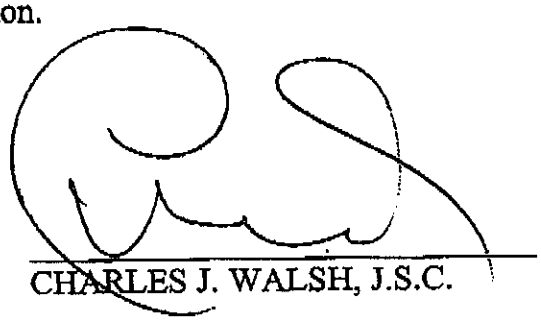
If the health care professional indicates that he or she would have recommended the use of phen-fen and would have willingly prescribed it upon advising of the potential valvular disease risks, a more complex inquiry is necessary. If the plaintiff denies that he or she would have taken the drug based on

those warnings, then the matter will be presented to a jury with the plaintiff bearing the burden of proof on this causation issue. *Sharpe*, 314 N.J. Super. at 63; **N.J.R.Evid.** 301.[15]

V

For the reasons discussed in this Opinion, Wyeth's motion is denied. Consequently, the heeding presumption will be applied in the five (5) named cases and the eight (8) back up cases. Should Wyeth produce evidence which rebuts the heeding presumption, the burden of proof is on each plaintiff to establish that any failure to warn their health care professional of the risk of valvular disease was a proximate cause of their injury.

An Order is enclosed with this Opinion.



CHARLES J. WALSH, J.S.C.

[15] The defendant may present evidence such that reasonable minds could differ as to whether the warning, if given, would have been heeded. According to *Sharpe*, this can be accomplished in several ways: first, "by offering evidence concerning the plaintiff's knowledge of the very risk that the absent warning was supposed to address"; second, by introducing evidence that the plaintiff would not have been motivated to heed the warning given by the physician; and third, by introducing evidence of plaintiff's attitudes and conduct that demonstrates an indifference to safety warnings generally. *Sharpe*, 314 N.J. Super. at 74.